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| 10/736,191      | 12/15/2003  | Robert A. Rowland III | 17090.002001        | 4366             |

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EXAMINER

GIBSON, ROY DEAN

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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3739

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/736,191

Applicant(s)

ROWLAND, ROBERT A.

Examiner

Roy D. Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-11 and 12-24 is/are rejected.
- 7) ☐ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 U.S.C. § 112***

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what the "other device" is since none has been claimed or recited in the preamble of claim 8 or 13.

### ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

- A person shall be entitled to a patent unless --  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 16 and 18-24 are rejected under 35 U.S.C. 102(b) as anticipated by Courtnage et al. (2002/0143373).

As to claim 1, Courtnage et al. disclose a method of treating infections comprising:

- (a) irradiating the suspected area with light from laser diodes or LEDs to cause a rapid temperature increase;
- (b) discontinuing the irradiation; and
- (c) assessing the suspected area for occurrence of infection: see [0011], [0012], [0017] - [0023], [0042] - [0043] and [0052] - [0055].

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As to claims 2-3, Courtnage et al. further disclose the heating is continued until a predetermined temperature is reached, sustained at the predetermined temperature for a period of time, prior to disconnecting the power source: see [0054-0055].

As to claims 4-6, the examiner maintains that it would have been inherent in the process for the operator or doctor to have a dialogue with the patient to determine his degree of discomfort, and act according as claimed.

As to claim 7, Courtnage et al. further disclose repeating steps (a) - (c) if the assessing suggests the treatment is further needed (inherent in the process: see [0054-0055]).

As to claims 8-11, 13, 14 and 16, Courtnage et al. further disclose an apparatus, comprising:

a heat transfer element having a surface (Figure 1, contact layer # 120) and a thermal energy source (laser diodes or LEDs) which is an integral part of the heat transfer element for altering its temperature as required and wherein the heat transfer element is configured to a shape of a target area (Figure 3 and [0042-0043]).

Further to claim 11, Courtnage et al. disclose a mechanism for thermographic recording of the treatment temperature: see [0038] and [0044].

Further to claim 13, Courtnage et al. disclose an input for sensing and reporting electromyographic data related to the treatment area: see [0038].

Further to claim 14, Courtnage et al. disclose an insulating element (layer 120) underlying the laser diode array: see [0036].

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Further to claim 16, the examiner maintains that it would be inherent in the design of the heat source to be able to replace a laser diode, etc.

As to claims 18-24, Courtnage et al. further disclose a method for using an apparatus for inhibiting infections essentially as claimed above: see [0011], [0012], [0017] - [0023], [0042] - [0043] and [0052] - [0055].

Claims 1-10, 13-16, 18, 19, 21 and 23-24 are rejected under 35 U.S.C. 102(b) as anticipated by Augustine et al. (6,468,295).

As to claim 1, Augustine et al. disclose a method of treating infections comprising:

- (a) irradiating the suspected area with heat from a heating coil (51) to cause a rapid temperature increase;
- (b) discontinuing the irradiation; and
- (c) assessing the suspected area for occurrence of infection (col. 1, lines 13-55, col. 4, lines 6-19, col. 4, line 61-col. 5, line 20).

As to claims 2-3, Augustine et al. further disclose the heating is continued until a predetermined temperature is reached, sustained at the predetermined temperature for a period of time, prior to disconnecting the power source (inherent in the process).

As to claims 4-6, the examiner maintains that it would have been inherent in the process for the operator or doctor to have a dialogue with the patient to determine his degree of discomfort, and act according as claimed.

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As to claim 7, Augustine et al. further disclose repeating steps (a) - (c) if the assessing suggests the treatment is further needed (inherent in the process).

As to claims 8-10, Augustine et al. disclose an apparatus comprising a heat transfer element (encapsulant with a surface and with integral heating coil 51) and a thermal energy source (32 with heating coil 51) which alters the temperature of the heat transfer element, wherein the heat transfer element is configured to a shape to fit over the wound or target area (Figures 4, 8 and 9 and col. 4, lines 6-10 and col. 5, lines 3-20).

As to claim 13, Augustine et al. disclose a touch switch which with an input of pressure turns off the power to the coil (col. 5, lines 3-9).

As to claim 14, Augustine et al. disclose an insulating element ( Figure 5, # 15 and col. 4, lines 20-31).

As to claim 15, Augustine et al. disclose a positioning element (Figure 6, # 34 and col. 4, lines 49-60).

As to claims 16, Augustine et al. disclose the thermal energy source (detachable heater 32) is separately replaceable (col. 4, lines 6-9).

As to claims 18, 19, 21, 23 and 24, Augustine et al. disclose a method for using an apparatus for inhibiting infection comprising essentially as claimed above (col. 1, lines 13-55, col. 4, lines 6-19, col. 4, line 61-col. 5, line 20).

***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Courtnage et al. In the embodiment of Figure 4, Courtnage et al. disclose a temperature sensor for measuring the temperature of the treatment area and for providing a signal to regulate the activity of the light source: see [0055]. Therefore, it would have been obvious to one of ordinary skill in the art, to provide such a sensor with the configuration of Figure 1, to provide the same temperature feedback and control function.

***Allowable Subject Matter***

Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Danek (2002/0165529) discloses a method and apparatus for non-invasive energy delivery which anticipates claims 8, 10, 11 and 13-16; and Bell et

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al. disclose a portable fluid therapy device which anticipates claims 8, 10, 11, and 13-16.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Roy D. Gibson  
Primary Examiner  
Art Unit 3739

April 1, 2005